

Attorney Docket No. 12777.BUS01

**MERCHANT & GOULD P.C.**  
**United States Patent Application**  
**COMBINED DECLARATION AND POWER OF ATTORNEY**

As a below named inventor I hereby declare that: my residence, post office address and citizenship are as stated below next to my name; that

I verily believe I am the original, first and sole inventor (if only one name is listed below) or a joint inventor (if plural inventors are named below) of the subject matter which is claimed and for which a patent is sought on the invention entitled: A METHOD FOR DETECTING MYCOBACTERIUM TUBERCULOSIS BY PCR AMPLIFICATION REP 13E12 REPEATED SEQUENCE

The specification of which

- a.  is attached hereto  
 b.  was filed on \_\_\_\_\_ as application serial no. \_\_\_\_\_ filed \_\_\_\_\_ and was amended on \_\_\_\_\_ (if applicable) (in the case of a PCT-filed application) described and claimed in international no. \_\_\_\_\_ and as amended on \_\_\_\_\_ (if any), which I have reviewed and for which I solicit a United States patent.

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I hereby claim foreign priority benefits under Title 35, United States Code, § 119/365 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on the basis of which priority is claimed:

- a.  no such applications have been filed.  
 b.  such applications have been filed as follows:

FOREIGN APPLICATION(S), IF ANY, CLAIMING PRIORITY UNDER 35 USC § 119			
COUNTRY	APPLICATION NUMBER	DATE OF FILING (day, month, year)	DATE OF ISSUE (day, month, year)
KOREA	10-2000-7984	19-FEBRUARY-2000	
ALL FOREIGN APPLICATION(S), IF ANY, FILED BEFORE THE PRIORITY APPLICATION(S)			
COUNTRY	APPLICATION NUMBER	DATE OF FILING (day, month, year)	DATE OF ISSUE (day, month, year)

I hereby claim the benefit under Title 35, United States Code, § 120/365 of any United States and PCT international application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, § 112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, § 1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application.

U.S. APPLICATION NUMBER	DATE OF FILING (day, month, year)	STATUS (patented, pending, abandoned)

I hereby claim the benefit under Title 35, United States Code § 119(e) of any United States provisional application(s) listed below:

U.S. PROVISIONAL APPLICATION NUMBER	DATE OF FILING (Day, Month, Year)

I acknowledge the duty to disclose information that is material to the patentability of this application in accordance with Title 37, Code of Federal Regulations, § 1.56 (reprinted below):

**§ 1.56 Duty to disclose information material to patentability.**

(a) A patent by its very nature is affected with a public interest. The public interest is best served, and the most effective patent examination occurs when, at the time an application is being examined, the Office is aware of and evaluates the teachings of all information material to patentability. Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section. The duty to disclose information exists with respect to each pending claim until the claim is canceled or withdrawn from consideration, or the application becomes abandoned. Information material to the patentability of a claim that is canceled or withdrawn from consideration need not be submitted if the information is not material to the patentability of any claim remaining under consideration in the application. There is no duty to submit information which is not material to the patentability of any existing claim. The duty to disclose all information known to be material to patentability is deemed to be satisfied if all information known to be material to patentability of any claim issued in a patent was cited by the Office or submitted to the Office in the manner prescribed by §§ 1.97(b)-(d) and 1.98. However, no patent will be granted on an application in connection with which fraud on the Office was practiced or attempted or the duty of disclosure was violated through bad faith or intentional misconduct. The Office encourages applicants to carefully examine:

- (1) prior art cited in search reports of a foreign patent office in a counterpart application, and
- (2) the closest information over which individuals associated with the filing or prosecution of a patent application believe any pending claim patentably defines, to make sure that any material information contained therein is disclosed to the Office.

(b) Under this section, information is material to patentability when it is not cumulative to information already of record or being made of record in the application, and

- (1) It establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim or
- (2) It refutes, or is inconsistent with, a position the applicant takes in:
  - (i) Opposing an argument of unpatentability relied on by the Office, or
  - (ii) Asserting an argument of patentability.

A prima facie case of unpatentability is established when the information compels a conclusion that a claim is unpatentable under the preponderance of evidence, burden-of-proof standard, giving each term in the claim its broadest reasonable construction consistent with the specification, and before any consideration is given to evidence which may be submitted in an attempt to establish a contrary conclusion of patentability.

(c) Individuals associated with the filing or prosecution of a patent application within the meaning of this section are:

- (1) Each inventor named in the application;
- (2) Each attorney or agent who prepares or prosecutes the application; and

(3) Every other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application.

(d) Individuals other than the attorney, agent or inventor may comply with this section by disclosing information to the attorney, agent, or inventor.

(e) In any continuation-in-part application, the duty under this section includes the duty to disclose to the Office all information known to the person to be material to patentability, as defined in paragraph (b) of this section, which became available between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

I hereby appoint the following attorney(s) and/or patent agent(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith:

Albrecht, John W.	Reg. No. 40,481	Leon, Andrew J.	Reg. No. 46,869
Ali, M. Jeffer	Reg. No. 46,359	Leonard, Christopher J.	Reg. No. 41,940
Anderson, Gregg I.	Reg. No. 28,828	Liepa, Mara E.	Reg. No. 40,066
Batzli, Brian H.	Reg. No. 32,960	Lindquist, Timothy A.	Reg. No. 40,701
Beard, John L.	Reg. No. 27,612	Lycke, Lawrence E.	Reg. No. 38,540
Berns, John M.	Reg. No. 43,496	Mayfield, Denise L.	Reg. No. 33,732
Black, Bruce E.	Reg. No. 41,622	McDonald, Daniel W.	Reg. No. 32,044
Branch, John W.	Reg. No. 41,633	McIntyre, Jr., William F.	Reg. No. 44,921
Bremer, Dennis C.	Reg. No. 40,528	Mitchem, M. Todd	Reg. No. 40,731
Bruess, Steven C.	Reg. No. 34,130	Mueller, Douglas P.	Reg. No. 30,300
Byrne, Linda M.	Reg. No. 32,404	Nichols, A. Shane	Reg. No. 43,836
Campbell, Keith	Reg. No. P-46,597	Pauly, Daniel M.	Reg. No. 40,123
Carlson, Alan G.	Reg. No. 25,959	Phillips, Bryan K.	Reg. No. P-46,990
Caspers, Philip P.	Reg. No. 33,227	Phillips, John B.	Reg. No. 37,206
Chiapetta, James R.	Reg. No. 39,634	Prendergast, Paul	Reg. No. 46,068
Clifford, John A.	Reg. No. 30,247	Pytel, Melissa J.	Reg. No. 41,512
Coldren, Richard J.	Reg. No. 44,084	Qualey, Terry	Reg. No. 25,148
Daignault, Ronald A.	Reg. No. 25,968	Reich, John C.	Reg. No. 37,703
Daley, Dennis R.	Reg. No. 34,994	Reiland, Earl D.	Reg. No. 25,767
Dalglash, Leslie E.	Reg. No. 40,579	Samuels, Lisa A.	Reg. No. 43,080
Daulton, Julie R.	Reg. No. 36,414	Schmaltz, David G.	Reg. No. 39,828
DeVries Smith, Katherine M.	Reg. No. 42,157	Schuman, Mark D.	Reg. No. 31,197
DiPietro, Mark J.	Reg. No. 28,707	Schumann, Michael D.	Reg. No. 30,422
Edell, Robert T.	Reg. No. 20,187	Scull, Timothy B.	Reg. No. 42,137
Epp, Ryan, Sandra	Reg. No. 39,667	Sebald, Gregory A.	Reg. No. 33,280
Glanee, Robert J.	Reg. No. 40,620	Skoog, Mark T.	Reg. No. 40,178
Goggin, Matthew J.	Reg. No. 44,125	Spellman, Steven J.	Reg. No. 45,124
Golla, Charles E.	Reg. No. 26,896	Stoll-DeBell, Kirstin L.	Reg. No. 43,164
Gorman, Alan G.	Reg. No. 38,472	Sumner, John P.	Reg. No. 29,114
Gould, John D.	Reg. No. 18,223	Swenson, Erik G.	Reg. No. 45,147
Gregson, Richard	Reg. No. 41,804	Tellekson, David K.	Reg. No. 32,314
Gresens, John J.	Reg. No. 33,112	Trembath, Jon R.	Reg. No. 38,344
Hamer, Samuel A.	Reg. No. 46,754	Tuchman, Ido	Reg. No. 45,924
Hanire, Curtis B.	Reg. No. 29,165	Tunheim, Marcia A.	Reg. No. 42,189
Harrison, Kevin C.	Reg. No. P-46,759	Underhill, Albert L.	Reg. No. 27,403
Hertzberg, Brett A.	Reg. No. 42,660	Vandenburgh, J. Derek	Reg. No. 32,179
Hillaon, Randall A.	Reg. No. 31,838	Wahl, John R.	Reg. No. 33,044
Holzer, Jr., Richard J.	Reg. No. 42,668	Weaver, Karrie G.	Reg. No. 43,245
Johnston, Scott W.	Reg. No. 39,721	Welter, Paul A.	Reg. No. 20,890
Kadievitch, Natalie D.	Reg. No. 34,196	Whipps, Brian	Reg. No. 43,261
Karjeker, Shaukat	Reg. No. 34,049	Whitaker, John E.	Reg. No. 42,222
Kastelic, Joseph M.	Reg. No. 37,160	Wickhem, J. Scot	Reg. No. 41,376
Kettelberger, Denise	Reg. No. 33,924	Williams, Douglas J.	Reg. No. 27,054
Keys, Jeramie J.	Reg. No. 42,724	Withers, James D.	Reg. No. 40,376
Knearl, Homer L.	Reg. No. 21,197	Witt, Jonelle	Reg. No. 41,980
Kowalchyk, Alan W.	Reg. No. 31,535	Wu, Tong	Reg. No. 43,361
Kowalchyk, Katherine M.	Reg. No. 36,848	Xu, Min S.	Reg. No. 39,536
Lacy, Paul E.	Reg. No. 38,946	Zeuli, Anthony R.	Reg. No. 45,255
Larson, James A.	Reg. No. 40,443		

I hereby authorize them to act and rely on instructions from and communicate directly with the person/assignee/attorney/firm/ organization who/which first sends/sent this case to them and by whom/which I hereby declare that I have consented after full disclosure to be represented unless/until I instruct Merchant & Gould P.C. to the contrary.

Please direct all correspondence in this case to Merchant & Gould P.C. at the address indicated below:

Merchant & Gould P.C.  
P.O. Box 2903  
Minneapolis, MN 55402-0903



I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statement may jeopardize the validity of the application or any patent issued thereon.

2	Full Name Of Inventor	Family Name LEE	First Given Name Tae-Yoon	Second Given Name
0	Residence & Citizenship	City Daegu-shi	State or Foreign Country KOREA	Country of Citizenship KOREA
1	Mailing Address	Address Main Bldg, STE 512, Yeungnam University Col. Med., 317-1, Daemyung-dong, Nam-gu	City Daegu-shi	State & Zip Code/Country KOREA

Signature of Inventor 201:

Date: January 22, 2001

2	Full Name Of Inventor	Family Name KIM	First Given Name Sung-Kwang	Second Given Name
0	Residence & Citizenship	City Daegu-shi	State or Foreign Country KOREA	Country of Citizenship KOREA
2	Mailing Address	Address Main Bldg, STE 512, Yeungnam University Col. Med., 317-1, Daemyung-dong, Nam-gu	City Daegu-shi	State & Zip Code/Country KOREA

Signature of Inventor 202:

Date: January 22, 2001

2	Full Name Of Inventor	Family Name LEE	First Given Name Jong-Seok	Second Given Name
0	Residence & Citizenship	City Daegu-shi	State or Foreign Country KOREA	Country of Citizenship KOREA
3	Mailing Address	Address Main Bldg, STE 512, Yeungnam University Col. Med., 317-1, Daemyung-dong, Nam-gu	City Daegu-shi	State & Zip Code/Country KOREA

Signature of Inventor 203:

Date: JANUARY 22, 2001

2	Full Name Of Inventor	Family Name LEE	First Given Name Jai-Youi	Second Given Name
0	Residence & Citizenship	City Daegu-shi	State or Foreign Country KOREA	Country of Citizenship KOREA
4	Mailing Address	Address 1370, Sankeok-dong, Book-gu	City Daegu-shi	State & Zip Code/Country KOREA

Signature of Inventor 204:

Date: January 22, 2001

**SMALL BUSINESS****VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY STATUS  
(37 C.F.R. 1.9(f)) - SMALL BUSINESS CONCERN**

I hereby declare that I am

- a)  the owner of the small business concern identified below:  
 b)  an official of the small business concern empowered to act on behalf of the concern identified below:

NAME OF CONCERN: BIOGENIA CO., LTD.  
 ADDRESS OF CONCERN: Owner Venture Bldg. Ste 409  
 1661, Bongchun-dong, Kwanack-gu  
 Seoul, KOREA

I hereby declare that the above identified small business concern qualifies as a small business concern as defined in 13 C.F.R. 121.801-805, and reproduced in 37 C.F.R. 1.9(d), for purposes of paying reduced fees under Section 41(a) and (b) of Title 35, United States Code, in that the number of employees of the concern, including those of its affiliates, does not exceed 500 persons. For purposes of this statement, (1) the number of employees of the business concern is the average over the previous fiscal year of the concern of the persons employed on a full-time, part-time or temporary basis during each of the pay periods of the fiscal year, and (2) concerns are affiliates of each other when either, directly or indirectly, one concern controls or has the power to control the other, or a third party or parties controls or has the power to control both.

I hereby declare that rights under contract or law have been conveyed to and remain with the small business concern identified above with regard to the invention, entitled A METHOD FOR DETECTING MYCOBACTERIUM TUBERCULOSIS BY PCR AMPLIFICATION REP [3E12 REPEATED SEQUENCE by inventor(s) LEE, TAE-YOON; KIM, SUNG-KWANG; LEE, JONG-SOK; LEE, JAI-YOUL described in

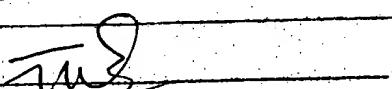
- a)  the specification filed herewith.  
 b)  provisional application serial no. \_\_\_\_\_, filed \_\_\_\_\_.  
 c)  non-provisional application serial no. \_\_\_\_\_, filed \_\_\_\_\_.  
 d)  patent no. \_\_\_\_\_, issued \_\_\_\_\_.  
 If the rights held by the above-identified small business concern are not exclusive, each individual, concern or organization having rights to the invention is listed below\* and no rights to the invention are held by any person, other than the inventor, who could not qualify as an independent inventor under 37 C.F.R. 1.9(c) or by any concern which would not qualify as a small business concern under 37 C.F.R. 1.9(d) or a nonprofit organization under 37 C.F.R. 1.9(e).

NAME: \_\_\_\_\_  
 ADDRESS: \_\_\_\_\_  
 a)  INDIVIDUAL      b)  SMALL BUSINESS CONCERN      c)  NONPROFIT ORGANIZATION

NAME: \_\_\_\_\_  
 ADDRESS: \_\_\_\_\_  
 a)  INDIVIDUAL      b)  SMALL BUSINESS CONCERN      c)  NONPROFIT ORGANIZATION

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 C.F.R. 1.27(g)(2))

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereof, or any patent to which this verified statement is directed.

NAME: \_\_\_\_\_  
 TITLE: \_\_\_\_\_  
 ADDRESS: \_\_\_\_\_  
 SIGNATURE:   
 Date: January 22, 2001



M&amp;G 12777.8US01

**INDEPENDENT INVENTOR(S)****VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY STATUS (37 C.F.R. 1.9(f)) - INDEPENDENT INVENTOR**

As a below named inventor, I hereby declare that I qualify as an independent inventor as defined in 37 C.F.R. 1.9(c) for purposes of paying reduced fees under Section 41(a) and (b) of Title 35, United States Code, to the Patent and Trademark Office with regard to the invention entitled A METHOD FOR DETECTING MYCOBACTERIUM TUBERCULOSIS BY PCR AMPLIFICATION REP 13E12 REPEATED SEQUENCE described in

- a)  the specification filed herewith.
- b)  provisional application serial no. \_\_\_\_\_, filed \_\_\_\_\_.
- c)  non-provisional application serial no. \_\_\_\_\_, filed \_\_\_\_\_.
- d)  patent no. \_\_\_\_\_, issued \_\_\_\_\_.

I have not assigned, granted, conveyed or licensed and am under no obligation under contract or law to assign, grant, convey or license, any rights in the invention to any person who could not be classified as an independent inventor under 37 C.F.R. 1.9(c) if that person has made the invention, or to any concern which would not qualify as a small business concern under 37 C.F.R. 1.9(d) or a nonprofit organization under 37 C.F.R. 1.9(e).

Each person, concern or organization to which I have assigned, granted, conveyed, or licensed or am under obligation under contract or law to assign, grant, convey, or license any rights in the invention is listed below:

- a)  no such person, concern, or organization
- b)  persons, concerns or organizations listed below\*

NAME	<u>BIOGENIA CO., LTD.</u>		
ADDRESS	Owner: Venture Bldg. Ste 409, 1661, Bongchun-dong, Kwanack-gu, Seoul, KOREA		
	a) <input type="checkbox"/> INDIVIDUAL	b) <input checked="" type="checkbox"/> SMALL BUSINESS CONCERN	c) <input type="checkbox"/> NONPROFIT ORGANIZATION
NAME	<u>LEE, Tae-Yoon</u>		
ADDRESS	Main Bldg, STE 512, Yeungnam University Col. Med., 317-1, Daemyung-dong, Nam-gu, Daegu-shi, KOREA		
	a) <input checked="" type="checkbox"/> INDIVIDUAL	b) <input type="checkbox"/> SMALL BUSINESS CONCERN	c) <input type="checkbox"/> NONPROFIT ORGANIZATION

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 C.F.R. 1.27(g)(2))

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereof, or any patent to which this verified statement is directed.

KIM, Sung-Kwang	LEE, Jong-Seok	LEE, Jai-Youl
NAME OF INVENTOR	NAME OF INVENTOR	NAME OF INVENTOR
<u>235826</u>	<u>01 313</u>	<u>01 2409</u>
Signature of Inventor	Signature of Inventor	Signature of Inventor

Date	Date	Date	Date
January 22, 2001	January 22, 2001	January 22, 2001	January 22, 2001



M&amp;G 12777.8US01

**INDEPENDENT INVENTOR(S)****VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY STATUS (37 C.F.R. 1.9(f)) - INDEPENDENT INVENTOR**

As a below named Inventor, I hereby declare that I qualify as an independent inventor as defined in 37 C.F.R. 1.9(c) for purposes of paying reduced fees under Section 41(a) and (b) of Title 35, United States Code, to the Patent and Trademark Office with regard to the invention entitled A METHOD FOR DETECTING MYCOBACTERIUM TUBERCULOSIS BY PCR AMPLIFICATION REP 13E12 REPEATED SEQUENCE described in

- a)  the specification filed herewith.
- b)  provisional application serial no. \_\_\_\_\_, filed \_\_\_\_\_.
- c)  non-provisional application serial no. \_\_\_\_\_, filed \_\_\_\_\_.
- d)  patent no. \_\_\_\_\_, issued \_\_\_\_\_.

I have not assigned, granted, conveyed or licensed and am under no obligation under contract or law to assign, grant, convey or license, any rights in the invention to any person who could not be classified as an independent inventor under 37 C.F.R. 1.9(c) if that person has made the invention, or to any concern which would not qualify as a small business concern under 37 C.F.R. 1.9(d) or a nonprofit organization under 37 C.F.R. 1.9(e).

Each person, concern or organization to which I have assigned, granted, conveyed, or licensed or am under obligation under contract or law to assign, grant, convey, or license any rights in the invention is listed below:

- a)  no such person, concern, or organization
- b)  persons, concerns or organizations listed below\*

NAME	BIOGENIA CO., LTD.,		
ADDRESS	Owner Venture Bldg. Ste 409, 1661, Bongchun-dong, Kwanack-gu, Seoul, KOREA		
	a) <input type="checkbox"/> INDIVIDUAL      b) <input checked="" type="checkbox"/> SMALL BUSINESS CONCERN    c) <input type="checkbox"/> NONPROFIT ORGANIZATION		

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 C.F.R. 1.27(g)(2))

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereof, or any patent to which this verified statement is directed.

LEE, Tae-Yoon

NAME OF INVENTOR	NAME OF INVENTOR	NAME OF INVENTOR	NAME OF INVENTOR
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Signature of Inventor	Signature of Inventor	Signature of Inventor	Signature of Inventor
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Date	Date	Date	Date
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January 22 2001

